Substances	Limitations
* * *	* * * *
High-purity furnace black (CAS Reg. No. 1333–86–4) containing total polynuclear aromatic hydrocarbons not to exceed 0.5 parts per million, and benzo[a]pyrene not to exceed 5.0 parts per billion, as determined by a method entitled ''Determination of PAH Content of Carbon Black,'' dated July 8, 1994, as developed by the Cabot Corp., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.	For use at levels not to exceed 2.5 percent by weight of the polymer.
* * *	* * * *

Dated: May 2, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–12156 Filed 5–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Medicated Feed Applications; Semduramicin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for revised assay limits for Type C medicated semduramicin chicken feed to 80 to 110 percent of labeled claim.

EFFECTIVE DATE: May 9, 1997.

FOR FURTHER INFORMATION CONTACT: William G. Marnane, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0678.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed supplemental NADA 140–940, which provides for revising the assay limits for Type C medicated chicken feed containing Aviax™ (semduramicin sodium) from 85 to 110 percent of labeled claim to 80 to 110 percent. The supplemental NADA is approved as of April 8, 1997, and the regulations are amended in 21 CFR 558.4(d) to reflect the approval.

Revision of the assay limits for a Type C medicated feed is based on the evaluation of the assay procedure used to analyze the feed and analysis of the assays of those feeds. The initial assay limits were established based on the results of the method trial. Evaluation of the feeds used in the market support trials, comparable to commercial manufacturing operations, support a wider assay range. This action did not require reevaluation of the safety and effectiveness data supporting the original approval. Therefore, a freedom of information summary is not required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.4 [Amended]

2. Section 558.4 *Medicated feed applications* is amended in paragraph (d), in the table entitled ''Category I,'' in the entry for ''Semduramicin,'' in the last column by removing the assay limits ''85–110'' and adding in its place ''80–110.''

Dated: April 30, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–12257 Filed 5–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 898

[Docket No. 94N–0078]

Medical Devices; Establishment of a Performance Standard for Electrode Lead Wires and Patient Cables

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing a performance standard for electrode lead wires and patient cables. The agency is taking this action because it has determined that a performance standard is needed to prevent electrical connections between patients and electrical power sources. The final rule will substantially reduce the risk of electrocution from unprotected electrode lead wires and patient cables.

DATES: This regulation is effective August 7, 1997, except that § 898.14 (21 CFR 898.14) is stayed pending Office of Management and Budget (OMB) clearance for information collection. FDA will announce the effective date of § 898.14 in the **Federal Register**. Submit written comments on the information collection provisions of this final rule by July 8, 1997.